

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Aaron W. Janke et al. Examiner: George R. Evanisko

Serial No.: 10/650,207 Group Art Unit: 3762

Filed: August 28, 2003 Docket: 279.093US3

For: HIGH IMPEDANCE ELECTRODE TIP

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on February 26, 2009, from the Final Rejection of claims 1-8 and 16-19 of the above-identified application, as set forth in the Final Office Action mailed on November 26, 2008.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of \$540.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of pending claims.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee,
CARDIAC PACEMAKERS, INC..

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on August 28, 2003 with claims 1-7. In an amendment and response filed September 24, 2004, claims 8-19 were added. In an Office Action mailed March 31, 2006, claims 9-15 were withdrawn. Accordingly claims 9-15 are presently withdrawn. A Final Office Action was mailed November 26, 2009. Claims 1-8 and 16-19 stand twice rejected, remain pending, and are the subject of the present Appeal.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action dated November 26, 2008.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Aspects of the present inventive subject matter include, but are not limited to, a high impedance electrode tip.

INDEPENDENT CLAIM 1

Claim 1 recites: A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising: an electrode tip (20), a mesh screen (30) disposed at a distal end of the electrode tip, a surface at the distal end of the electrode tip, a helix (100) disposed within said electrode, said helix adapted for travel along a radial axis of the electrode through said surface. (Fig. 4A and page 16, lines 17-27). The helix includes non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient. (Page 20, line 14 - page 21, line 16; and page 25, lines 2-8). A guiding mechanism (70) for directing movement of the fixation device during travel, and a movement assembly (14, 50), said movement assembly for providing movement to said fixation device. (Fig 4A and page 17, lines 10-26).

INDEPENDENT CLAIM 16

Claim 16 recites: A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising: an electrode tip (800); a mesh screen (808) disposed at a distal end of the electrode tip; a surface at the distal end of the electrode tip; and a fixation helix (802) disposed within said electrode, said fixation helix adapted for travel along a radial axis of the electrode through said surface. (Fig. 6 and page 24, lines 2-5). The fixation helix includes a non-soluble insulating material (804) coated on at least a portion of its outer surface so as to conform to the outer surface of the helix, the insulating material including an active ingredient. (Fig. 6 and page 20, line 14 - page 21, line 16; and page 24, lines 5-15; and page 25, lines 2-8).

This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and its legal equivalents for a complete statement of the invention.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-5, 7, and 8, were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping (US Pat. No. 4,886,074) in view of Dutcher et al. (U.S. Patent No. 5,217,028).

Whether claims 16-19 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping (US Pat. No. 4,886,074) in view of Dutcher et al. (U.S. Patent No. 5,217,028).

Whether claims 1-5, 7, and 8 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over Bisping (U.S. Patent No. 4,886,074) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Whether claims 16-19 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over Bisping (U.S. Patent No. 4,886,074) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Whether claims 1, 2, 3, 7, and 8 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265) in view of Dutcher et al. (U.S. Patent No. 5,217,028).

Whether claims 16-19 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265) in view of Dutcher et al. (U.S. Patent No. 5,217,028).

Whether claims 1, 2, 3, 7, and 8 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Grassi (U.S. Patent No. 4,624,265) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Whether claims 16-19 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Grassi (U.S. Patent No. 4,624,265) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Whether claims 4 and 5 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over either modified Grassi (U.S. Patent No. 4,624,265) rejected above in view of Bisping (U.S. Patent No. 4,886,074), Jammet (U.S. Patent No. 5,447,534), or Ocel et al. (U.S. Patent No. 5,837,006).

Whether claim 6 was properly rejected under 35 U.S.C. 103(a) as being unpatentable over either modified Bisping (U.S. Patent No. 4,886,074) or either modified Grassi et al. (U.S. Patent No. 4,624,265) as applied to claim 1 above and further in view of Ocel et al. (U.S. Patent No. 5,837,006) or Vachon (U.S. Patent No. 5,531,780).

7. ARGUMENT

A) The Applicable Law under 35 U.S.C. §103

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). To do that the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.*

The Fine court stated that:

Obviousness is tested by “what the combined teaching of the references would have suggested to those of ordinary skill in the art.” *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it “cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.” *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And “teachings of references can be combined only if there is some suggestion or incentive to do so.” *Id.* (emphasis in original).

The M.P.E.P. adopts this line of reasoning, stating that:

In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant’s disclosure. M.P.E.P. § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed.Cir. 1991)).

B) Discussion of the rejection of claims 1-5, 7, and 8, under 35 U.S.C. 103(a) as being unpatentable over Bisping (US Pat. No. 4,886,074) in view of Dutcher et al. (U.S. Patent No. 5,217,028).

Appellant traverses the rejection of claim 1. Appellant believes claim 1 is not obvious in view of the cited references since, even if combined, each limitation recited in the claim is not found in the cited combination. For instance, Appellant cannot find in the combination: a helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 1.

The Final Office Action states that Dutcher includes “a non-soluble coating containing a drug on a portion of the exterior surface of the lead (e.g. col. 2, lines 45-65, figure 5, 138, or 138 and 133).” (Page 3 of Final Office Action, 11/26/08). Appellant traverses this characterization of the Dutcher reference. That portion of the Dutcher reference discusses a sheath 133 on a wire 131 and a drug plug 138. The drug plug 138 is a plug of material filling the interior of wire 131. However, even if members 133 and 138 are combined they do not include: the insulating material including an active ingredient, as recited in claim 1. Sheath 133 does not include any active ingredient and drug plug 138 is not an insulating material that conforms to the outer surface of the helix. As described in the Dutcher reference: “The drug will be dispensed from the outer surface of plug 138 to the heart tissue as plug 138 is positioned in contacting relationship with the heart tissue.” (Col. 4, lines 53-56). Accordingly, the drug of drug plug 138 and sheath 133 are not part of a structure that includes a non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 1.

The Response to Arguments section of the Final Office Action states that “Dutcher shows in figures 5, 8, and 9, the plastic drug plug, 138/238, covering/coating a portion of the outer surface of the helix.” (Page 9 of Final Office Action). However, drug plug 138/238 does not cover or coat the outer surface of the helix so as to conform to the outer surface of the helix, as recited in claim 1.

The Response to Arguments further states that “Dutcher includes insulative coating, 133 or 233 (e.g. col. 3, line 57), that conforms to an outer surface of the helix and contains an active

ingredient from drug plug, 138, due to the migration of the drug from the plug or touching of the plug to insulative coating, 133 or 233.” (Page 10 of Office Action). However, claim 1 recites: the insulating material including an active ingredient. It does not recite that the drug is adjacent the insulating material. Also, as discussed above, the Dutcher reference describes that: “The drug will be dispensed from the outer surface of plug 138 to the heart tissue as plug 138 is positioned in contacting relationship with the heart tissue.” (Col. 4, lines 53-56). Thus, the Dutcher reference itself does not state that the drug is included or contained in the insulative coating 133.

Claims 2-5, 7, and 8 include each limitation of claim 1 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

C) Discussion of the rejection of claims 16-19 under 35 U.S.C. 103(a) as being unpatentable over Bisping (US Pat. No. 4,886,074) in view of Dutcher et al. (U.S. Patent No. 5,217,028).

Appellant traverses the rejection of claim 16. Appellant believes claim 16 is not obvious over the cited references since each limitation recited in the claim is not found in the cited combination. For instance, Appellant cannot find in the combination, a fixation helix including a non-soluble insulating material coated on at least a portion of its outer surface so as to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 16. The discussion above for claim 1 is incorporated herein by reference.

Claims 17-19 include each limitation of claim 16 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

D) Discussion of the rejection of claims 1-5, 7, and 8 under 35 U.S.C. §103(a) as being unpatentable over Bisping (U.S. Patent No. 4,886,074) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Appellant believes claim 1 is not obvious in view of the cited references since there is no reason or suggestion to combine the references.

Here, Altman discusses different coatings for an implantable device which is for “effective elimination of an arrhythmogenic site.” (Abstract). In contrast, Bisping relates to an

implantable electrode type lead assembly. (Abstract). Thus, there appears to be no motivation or reason to apply any of Altman's or Hoffman's discussions to the lead of Bisping, since they are used for generally different purposes.

In the Response to Arguments section, the Final Office Action states that "both Altman and Bisping are in the same field of endeavor, i.e. fixation helixes used to screw into the heart." (Page 10 of Final Office Action). However Bisping gives no indication of a need for any of the Objects of Invention described in Altman at col. 6, line 20 – col. 7 line 3, where the Altman disclosure discusses different purposes of the device to treat arrhythmogenic sites. Merely because Altman discusses a helix shape for the arrhythmogenic treatment device does not mean that his disclosure applies to a helix used for a completely different purpose, such as the Bisping helix, which is used as a fixation device to hold an electrode in place.

Regarding the Hoffman reference, the Hoffman reference discusses a lead having a hydrogel coating. (Abstract). It discusses nothing of an insulative coating for a helix. The Hoffman reference teaches away from such an application of the hydrogel coating. For instance, at col. 6, lines 7-12, Hoffman states that "It is not necessary to apply the hydrogel to the connectors, the pacing tip electrode, or the region of the lead that will be coiled into the subcutaneous area. If the pacing tip electrode were coated, tissue would not grow into the pores, thereby not providing firm stabilization of the lead at the tip."

Claims 2-5, 7, and 8 include each limitation of claim 1 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

E) Discussion of the rejection of claims 16-19 under 35 U.S.C. §103(a) as being unpatentable over Bisping (U.S. Patent No. 4,886,074) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Appellant traverses the rejection of claim 16. Appellant believes claim 16 is not obvious over the cited references since there is no reason or suggestion to combine the references. The discussion above for claim 1 is incorporated herein by reference.

Claims 17-19 include each limitation of claim 16 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

F) Discussion of the rejection of claims 1, 2, 3, 7, and 8 under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265) in view of Dutcher et al. (U.S. Patent No. 5,217,028).

Appellant believes claim 1 is not obvious over the cited references since each limitation recited in the claim is not found in the cited combination. For instance, Appellant cannot find in the combination: a helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 1.

As discussed above, the Dutcher reference discusses a sheath 133 on a wire 131 and a drug plug 138. However, even if combined, this does not read on the claimed: non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, “the insulating material including an active ingredient.” The discussion above regarding the Dutcher reference is incorporated herein by reference.

Claims 2-3, 7, and 8 include each limitation of claim 1 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

G) Discussion of the rejection of claims 16-19 under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265) in view of Dutcher et al. (U.S. Patent No. 5,217,028).

Appellant believes claim 16 is not obvious over the cited reference since each limitation recited in the claim is not found in the cited reference. For instance, Appellant cannot find in the combination: a fixation helix including a non-soluble insulating material coated on at least a portion of its outer surface so as to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 16. The discussion above for claim 1 is incorporated herein by reference.

Claims 17-19 include each limitation of claim 16 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

H) Discussion of the rejection of claims 1, 2, 3, 7, and 8 under 35 U.S.C. § 103(a) as being unpatentable over Grassi (U.S. Patent No. 4,624,265) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Appellant believes claim 1 is not obvious in view of the cited references since there is no reason or suggestion to combine the references.

Here, Altman discusses different coatings for an implantable device which is for “effective elimination of an arrhythmogenic site.” (Abstract). In contrast, Grassi relates to an implantable electrode for a pacemaker. (Abstract). Thus, there appears to be no motivation or reason to apply any of Altman’s discussion to the lead of Grassi, since they are used for generally different purposes. The Grassi disclosure gives no indication of a need for any of the Objects of Invention described in Altman at col. 6, line 20 – col. 7 line 3, where the Altman disclosure discusses different purposes of the device to treat arrhythmogenic sites. Merely because Altman discusses a helix shape for the arrhythmogenic treatment device does not mean that the disclosure applies to a helix used for a completely different purpose, such as the Grassi helix, which is used as a fixation device to hold an electrode in place.

Regarding the Hoffman reference, the Hoffman reference discusses a lead having a hydrogel coating. (Abstract). It discusses nothing of an insulative coating for a helix. The Hoffman reference teaches away from such an application of the hydrogel coating. For instance, at col. 6, lines 7-12, Hoffman states that “It is not necessary to apply the hydrogel to the connectors, the pacing tip electrode, or the region of the lead that will be coiled into the subcutaneous area. If the pacing tip electrode were coated, tissue would not grow into the pores, thereby not providing firm stabilization of the lead at the tip.”

Claims 2-3, 7, and 8 include each limitation of claim 1 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

I) Discussion of the rejection of claims 16-19 under 35 U.S.C. § 103(a) as being unpatentable over Grassi (U.S. Patent No. 4,624,265) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Appellant traverses the rejection of claim 16. Appellant believes claim 16 is not obvious over the cited references since there is no reason or suggestion to combine the references. The discussion above for claim 1 is incorporated herein by reference.

Claims 17-19 include each limitation of claim 16 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

J) Discussion of the rejection of claims 4 and 5 under 35 U.S.C. 103(a) as being unpatentable over Grassi (U.S. Patent No. 4,624,265) rejected above in view of Bisping (U.S. Patent No. 4,886,074), Jammet (U.S. Patent No. 5,447,534), or Ocel et al. (U.S. Patent No. 5,837,006).

Claims 4 and 5 depend from claim 1 and are not obvious over the cited references for the reasons discussed about regarding claim 1. Also, Appellant believes the Office Action has provided insufficient motivation to modify the cited reference. Appellant notes that the mere fact that a reference can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01. Reconsideration and allowance is respectfully requested.

K) Discussion of the rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over either modified Bisping (U.S. Patent No. 4,886,074) or either modified Grassi et al. (U.S. Patent No. 4,624,265) as applied to claim 1 above and further in view of Ocel et al. (U.S. Patent No. 5,837,006) or Vachon (U.S. Patent No. 5,531,780).

Claim 6 depends from claim 1 and is not obvious over the cited references for the reasons discussed about regarding claim 1. Also, Appellant believes the Office Action has provided insufficient motivation to modify the cited reference. Appellant notes that the mere fact that a reference can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16

USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01. Reconsideration and allowance is respectfully requested.

SUMMARY

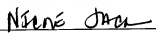
For the reasons argued above, claims 1-8 and 16-19 were not properly rejected under § 103. It is respectfully submitted that the art cited does not render the claims obvious and the claims are patentable over the cited art. Reversal of the rejection and allowance of the pending claims is respectfully requested.

Respectfully submitted,

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Date 4/27/09 By 
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: MS Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 21 day of April 2009.


Name


Signature

8. CLAIMS APPENDIX

1. A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising:
 - an electrode tip;
 - a mesh screen disposed at a distal end of the electrode tip;
 - a surface at the distal end of the electrode tip;
 - a helix disposed within said electrode, said helix adapted for travel along a radial axis of the electrode through said surface, the helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient;
 - a guiding mechanism for directing movement of the fixation device during travel; and
 - a movement assembly, said movement assembly for providing movement to said fixation device.
2. The distal tip electrode as recited in claim 1, wherein said helix comprises a fixation helix.
3. The distal tip electrode as recited in claim 1, wherein said movement assembly comprises a piston and a base.
4. The distal tip electrode as recited in claim 3, wherein the piston has a slot therein, and the base further comprises a knob, said slot for mating with said knob.
5. The distal tip electrode as recited in claim 4, wherein the slot is mated with said knob to form a stop mechanism for said fixation device.
6. The distal tip electrode as recited in claim 1, wherein the guiding mechanism includes a groove guide disposed within the mesh screen.

7. The distal tip electrode as recited in claim 1, wherein the active ingredient includes a medication.
8. The distal tip electrode of claim 1, wherein the active ingredient includes an anti-inflammatant, an anti-biotic, or an analgesic.
16. A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising:
- an electrode tip;
 - a mesh screen disposed at a distal end of the electrode tip;
 - a surface at the distal end of the electrode tip; and
 - a fixation helix disposed within said electrode, said fixation helix adapted for travel along a radial axis of the electrode through said surface, the fixation helix including a non-soluble insulating material coated on at least a portion of its outer surface so as to conform to the outer surface of the helix, the insulating material including an active ingredient.
17. The distal tip electrode of claim 16, wherein the active ingredient includes a medication.
18. The distal tip electrode of claim 16, wherein the active ingredient includes an anti-inflammatant, an anti-biotic, or an analgesic.
19. The distal tip electrode of claim 16, wherein the active ingredient includes an anti-inflammatant, an anti-biotic, an analgesic, a pain-reducing medication, a vitamin, or an anti-viral medication.

9. EVIDENCE APPENDIX

None.

10. RELATED PROCEEDINGS APPENDIX

None.